Prematurity Prevention Summit 2016

Evidenced-Based Practice Update:
Strategies to Prevent Preterm Birth

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Prevention of Preterm Birth

Utah Women and Newborn Quality Collaborative
Maternal Intervention Committee

Frank Powers, MD, Sean Esplin, MD, Julia Johnson, MPH
Prematurity Prevention Summit
LDS Hospital
October 24, 2016

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Acknowledgments

- Sean Esplin, MFM
- Erin Clark, MFM
- David Turok, OB-GYN, Family Planning
- Julia Johnson, UDOH

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Utah Women and Newborn Quality Collaborative (UWNQC)

- Statewide multi-stake holder network designed to improve perinatal outcomes in Utah
- **Mission:** "Improve maternal and neonatal outcomes through collaborative efforts centered around quality improvement methodology and data sharing"

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Preterm Birth

- 1 in 8 births in US (12%)
- Utah singleton PTB rate 9.5% (in 2010)
- Estimate cost in US $26 billion per year ($51,000 per infant)
- Leading cause responsible for 85% of all perinatal morbidity and mortality

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Risk Factors for Preterm Birth

- Personal history of preterm birth
  - Strongest
- Incidental Short Cervix
- Unintended pregnancy
- Short inter-pregnancy interval

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Focus on women with a history of SPTB

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Impact of Recurrent Preterm Birth

- 15% of all preterm births are recurrent preterm births
  - 75,000 of the 500,000 PTB in the US annually
- Interventions including progesterone reduce rate by up to 30%
  - Estimated that 10,000 PTB prevented annually*
- The only type of PTB that can be accurately predicted

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*Petrini et al. Obstet Gynecol 2005;105(2):267

Progesterone Therapy

- Meta-analysis of randomized trials
  - 7 trials of 17OHP to prevent recurrent PTB
  - Use 17 OHP 250 mg IM weekly beginning at 16-20 weeks
  - Risk for PTB < 37 wks - 1020 women enrolled
    - RR = 0.58, 95% CI = 0.48-0.70
  - Risk for infant with birth weight of < or =2.5 kg - 872 infants
    - RR = 0.62, 95% CI = 0.49-0.78
  - Risk of an infant diagnosed with intraventricular hemorrhage -458 infants
    - RR = 0.25, 95% CI = 0.08-0.82

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Vag P vs. 17 OHPC

- Prospective randomized trial for women with history of SPTB
  - 90 mg vaginal progesterone gel daily (n=253)
  - 250 mg 17 OHPC weekly (n=249)
  - Started at 14-18 weeks
- Inclusion
  - Singleton between 14 and 18 weeks gestation
  - History of previous SPTB
    - Included women who had cerclage in previous pregnancy

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Vag P vs. 17 OHPC

- Primary outcome GA at < 34 weeks gestation
  - Vag P 42/253 (16%)
  - 17 OHPC 64/249 (25.7%)
  - P = 0.02
  - OR 0.58 (95%CI 0.37-0.89)

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17 P
The Bottom Line

- Screen all patients for history of SPTB
  - Live birth between 20 weeks 0 days and 36 weeks 6 days
  - Any type of delivery after spontaneous labor, PPROM, Abruption or Silent cervical dilation
- For previous deliveries between 16 -24 weeks
  - Consider prophylactic cerclage

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17 P
The Bottom Line

- Progesterone therapy
  - 1st Line 17 OHPC
    - Dose is 250 mg IM weekly
    - Start at 16 weeks if possible but still some affect as late as 24 weeks
    - Use Makena if possible but may use compounded if insurance issue or allergy documented
  - 2nd Line Vaginal Progesterone
    - Natural progesterone 200 mg suppository
    - Crinone gel 90 mg nightly

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Progesterone Therapy
and…

- Not for twins or triplets
- Not for women with symptomatic labor unless previous history of PTB
- Still offer 17 OHPC even if last delivery was at term
- Progesterone and cervical shortening
  - Start treatment if not previously initiated
  - 17 OHPC vs vaginal progesterone

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How to get 17P

- Rx for 17-OH progesterone 250mg/ml
  - 250mg IM weekly 16-36 weeks
- ICD 10 "Supervision of pregnancy with history of preterm labor" (second, third, unspecified trimester)
  - O09.212, O09.213, O09.219
- Makena only FDA-approved formulation

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How to get 17P

- Cost $15,000 per pregnancy ($690 per injection)
- Co-pay and insurance coverage varies
- Patient assistance programs
  - Free for unfunded patients who meet eligibility
  - Co-pay assistance (Medicaid, Tricare not eligible)
- UWNQC recommends facility establishes protocol

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The role of cerclage

Which patient and when

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History of SPTB and Short Cervix

- Meta-analysis of 5 trials
- Women with a history of SPTB and short cervix (<2.5 cm) n=504
- Rate of PTB < 35 weeks
  - 28.4% (71/250) in the cerclage compared with 41.3% (105/254) in the no cerclage groups
  - (relative risk 0.70, 95% confidence interval 0.55– 0.89)
- Cerclage also significantly reduced
  - PTB < 37, 32, 28, and 24 weeks of gestation.
  - Composite perinatal mortality and morbidity (15.6% in cerclage compared with 24.8% in no cerclage groups; relative risk 0.64, 95% confidence interval 0.45– 0.91).

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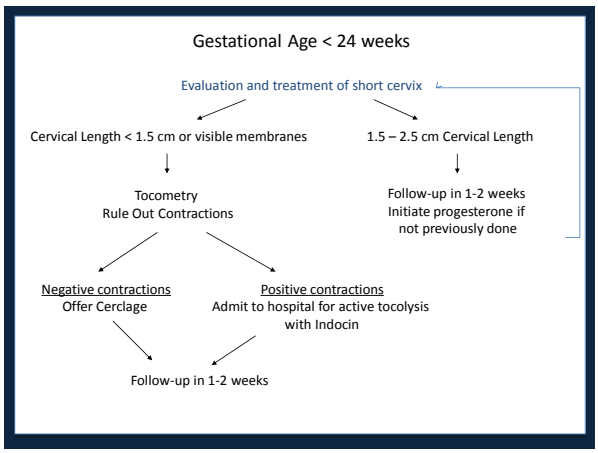
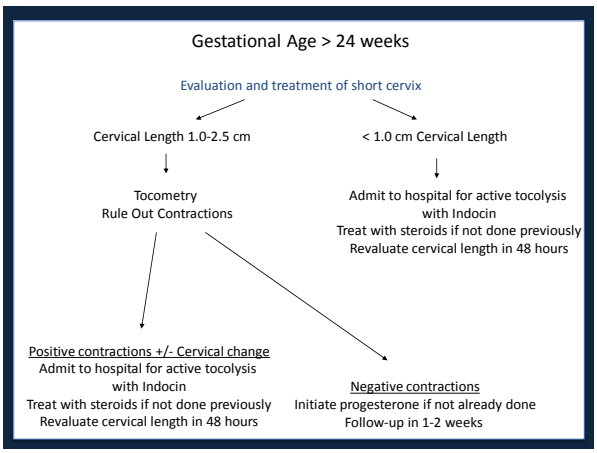
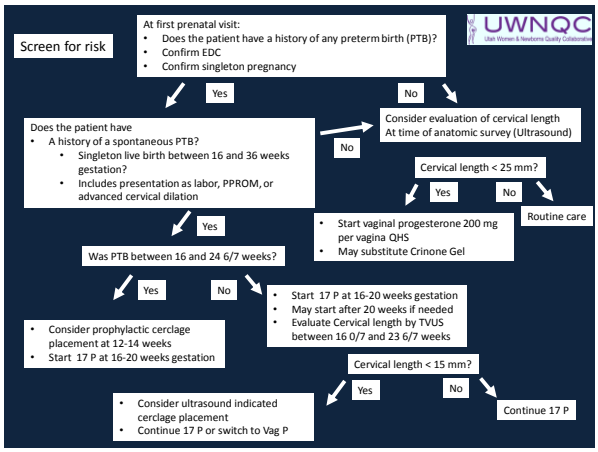
Berghella et al. Obstet Gynecol 2011; 117:663







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Thank You

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Transferring Smoothly: The State of Out-of-Hospital Birth Transfers in Utah

ERIN A. S. CLARK, MD
MATERNAL FETAL MEDICINE
The University of Utah
Department of Obstetrics & Gynecology

Disclosure

- I am an obstetrician…
- …An obstetrician sympathetic to a woman's right to choose where and how to deliver

Transitioning Smoothly

Acknowledgement of two truths is necessary in order to have this conversation:

- 1. Women are going to continue to choose to deliver at birth centers and at home.
- 2. Women are occasionally going to need transfer to a hospital for management of complications / concerns.

Transitioning Smoothly

- The relative rarity of the event only makes the topic more relevant, because it is hard to do something really well, when we only do it occasionally.

Objectives

- Introduce UWNQC Out-of-Hospital Birth Subcommittee
  - Mission, members, work-to-date
  - Tools derived from the collaborative
  - Opportunities for future work

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Out-of-Hospital Birth Subcommittee: Mission

First convened, November 2013

1) Analysis of the current state of out-of-hospital births in Utah

2) Identification of maternal and neonatal safety issues related to out-of-hospital birth and transfers

3) Creation of statewide action items

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Out-of-Hospital Birth Subcommittee: Members

- Multi-disciplinary team of stakeholders:
  - Obstetricians, pediatricians, nurses, CNMs, community midwives, hospital and public health administrators
- Open meeting (everyone welcome)
  - Second Tuesday, 3:00-4:30 pm, Dept. of Health (Highland)

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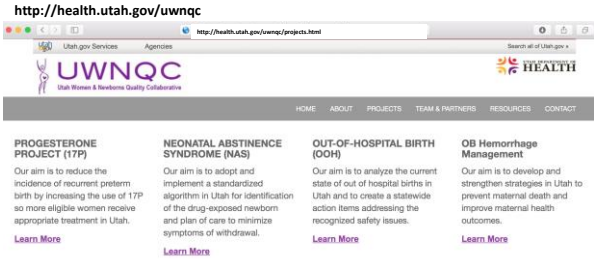
http://health.utah.gov/uwnqc



Informational Resources

- Utah Best Practice Guidelines: Transfer to Hospital from Planned Out-of-Hospital Birth
- Three Questions Debriefing Form
- Midwife Infographic
- Home Birth Summit Best Practice Guidelines: Transfer from Planned Home Birth to Hospital
- Planned Out-of-Hospital Births in Utah, 2010-2012: A Descriptive Review

Maternal Transfer Form

- UWNQC Maternal Transfer Form (Fillable)
- UWNQC Maternal Transfer Form (Printable)

Neonatal Transfer Form

- UWNQC Neonatal Transfer Form (Fillable)
- UWNQC Neonatal Transfer Form (Printable)

Hospital Specific Transfer Algorithms

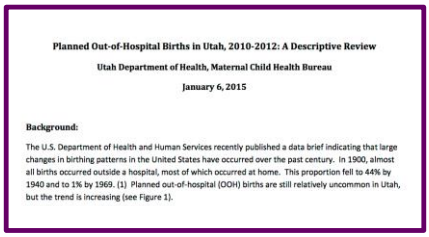
- Davis Hospital and Medical Center (Layton, UT)
- Intermountain Medical Center (Murray, UT)
- Jordan Valley Medical Center (West Jordan, UT)
- University of Utah Health Care (Salt Lake City, UT)

Hospital Specific Transfer Referral Guides

- Intermountain Medical Center (Murray, UT)
- Jordan Valley Medical Center (West Jordan, UT)

Out-of-Hospital Birth Resources

First Report on Planned Out-of-Hospital Births in Utah



Planned Out-of-Hospital Births in Utah, 2010-2012: A Descriptive Review

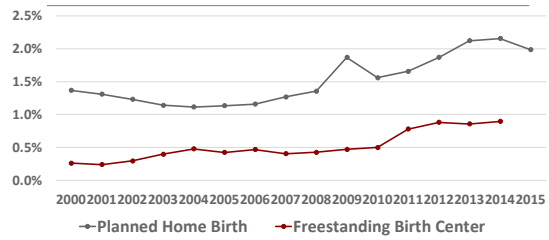
Utah Department of Health, Maternal Child Health Bureau

January 6, 2015

Background:

The U.S. Department of Health and Human Services recently published a data brief indicating that large changes in birthing patterns in the United States have occurred over the past century. In 1900, almost all births occurred outside a hospital, most of which occurred at home. This proportion fell to 44% by 1940 and to 1% by 1969. (1) Planned out-of-hospital (OOH) births are still relatively uncommon in Utah, but the trend is increasing (see Figure 1).

Planned Out-of-hospital Births, 2000-2015



Out-of-Hospital Birth Report, 2010-2012

- Descriptive statistics
- Notable limitations
  - Unable to identify intended out-of-hospital births who ultimately delivered in the hospital
  - Unable to identify intrapartum fetal deaths that occur in an out-of-hospital setting

→ *Changes in the birth and fetal death certificates*

Changes in Birth & Death Certificates

- Allows capture of intended out-of-hospital births that ultimately deliver in the hospital
- Oregon is the only other state to capture this information (unable to differentiate home vs. birth center)

☐ **Mother Transferred FROM ANOTHER BIRTHING FACILITY DURING LABOR/DELIVERY** (Hospital or Freestanding Birth Center)

If "Yes" Birthing Facility Name_____State_____

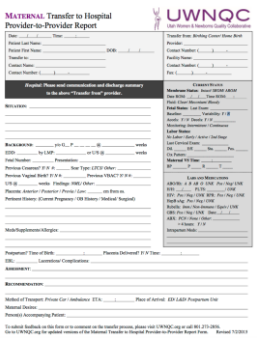
Mother transferred **TO** a hospital from an attempted home birth

☐ During Labor ☐ Postpartum (within 24 hrs of delivery ☐ Unknown

Snowden et al., NEJM, 2015

Transfer Forms: Maternal and Neonatal

- Communication tools
- Based on Home Birth Summit and work from other states
- SBAR format
  Situation, Background, Assessment, Recommendation
- Field-tested in an iterative process


MATERNAL Transfer to Hospital
Provider-to-Provider Report
UWNQC


NEONATAL Transfer to Hospital
Provider-to-Provider Report
UWNQC

Transfer Forms: Maternal and Neonatal

- How should we use these?
  - Encouraged communication tool
  - Facilitates SBAR oral communication
  - Option to fill out prior to transport as a concise summary
  - Option to fill out after arrival with the accepting medical team in the case of urgent transfers
  - Ensures correct information re: the transferring midwife

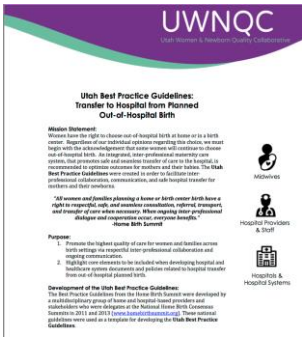
Home Birth Summit

The Future of Home Birth in the United States: Addressing Shared Responsibility

Best Practice Guidelines: Transfer from Planned Home Birth to Hospital

June 2016

- **Utah Best Practice Guidelines**
  - Based on national guidelines
  - Defines model practices
    - Midwife
    - Hospital provider and staff
    - Hospitals and hospital systems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Utah Best Practice Guidelines: Transfer to Hospital from Planned Out-of-Hospital Birth

Mission Statement:
Women have the right to choose out-of-hospital birth at home or in a birth center. Regardless of our individual opinions regarding this choice, we must begin with the acknowledgement that some women will continue to choose out-of-hospital birth. An integrated, inter-professional maternity care system, that promotes safe and seamless transfer of care to the hospital, is necessary to optimize outcomes for mothers and their babies. The **Utah Best Practice Guidelines** were created in order to facilitate inter-professional collaboration, communication, and safe hospital transfer for mothers and their newborns.

"All women and families planning a home or birth center birth have a right to respectful, safe, and seamless consultation, referral, transport, and transfer of care when necessary. When ongoing inter-professional dialogue and cooperation occur, everyone benefits."
-Home Birth Summit

Purpose:
1. Promote the highest quality of care for women and families across birth settings via respectful inter-professional collaboration and ongoing communication.
2. Highlight core elements to be included when developing hospital and healthcare system documents and policies related to hospital transfer from out-of-hospital planned birth.

Development of the Utah Best Practice Guidelines:
The Best Practice Guidelines from the Home Birth Summit were developed by a multidisciplinary group of home and hospital-based providers and consumers. Authors were delegates at the National Home Birth Consensus Summits in 2013 and 2015 (www.homebirthsummit.org). These national guidelines were used as a template for developing the **Utah Best Practice Guidelines**.

Midwives

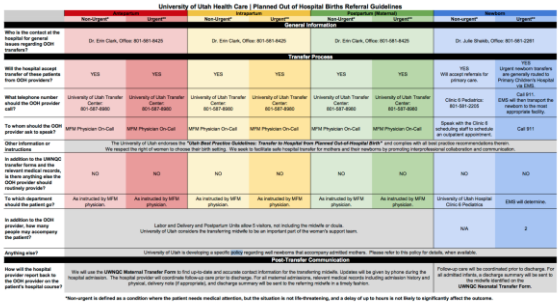
Hospital Providers & Staff

Hospitals & Hospital Systems

Helping Hospitals: A Transfer Algorithm

- Hospitals need to identify their transfer process

  What number should a transferring provider call?
  - -Maternal: Antepartum / Intrapartum / Postpartum
  - -Neonatal
  - -Non-urgent vs. urgent
- Our goal is to help each hospital define their process aand post on the UWNQC website for easy reference



University of Utah Health Care | Planned Out of Hospital Births Referral Guidelines

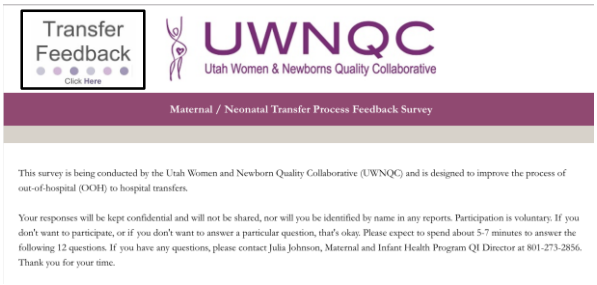
	Antepartum		Intrapartum		Postpartum (Maternal)		Newborn	
	Non-Urgent*	Urgent**	Non-Urgent*	Urgent**	Non-Urgent*	Urgent**	Non-urgent*	Urgent**
General Information								
Who is the contact at the hospital for general questions regarding OOH transfers?	Dr. Erin Clark, Office: 801-581-8429		Dr. Erin Clark, Office: 801-581-8425		Dr. Erin Clark, Office: 801-581-8425		Dr. Julie Shields, Office: 801-581-2261	
Transfer Process								
Will the hospital accept transfer of these patients from OOH providers?	YES	YES	YES	YES	YES	YES	YES Will accept referrals for primary care.	YES Urgent newborn transfers are generally routed to Primary Children's Hospital (PCH).
What telephone number should the OOH provider call?	University of Utah Transfer Center: 801-587-6960	University of Utah Transfer Center: 801-587-6960	University of Utah Transfer Center: 801-587-6960	University of Utah Transfer Center: 801-587-6960	University of Utah Transfer Center: 801-587-6960	University of Utah Transfer Center: 801-587-6960	Clinic-5 Pediatrics: 801-581-2205	EMS will then transport the newborn to the most appropriate facility.
To whom should the OOH provider ask to speak?	MFM Physician On-Call	MFM Physician On-Call	MFM Physician On-Call	MFM Physician On-Call	MFM Physician On-Call	MFM Physician On-Call	Speak with the Clinic-5 scheduler to arrange for an outpatient appointment.	Call 911
Other information or instructions	The University of Utah endorses the "**Utah Best Practice Guidelines: Transfer to Hospital from Planned Out-of-Hospital Birth**" and complies with all best practice recommendations therein. We respect the right of women to choose their birth setting. We seek to facilitate safe hospital transfer for mothers and their newborns by promoting interprofessional collaboration and communication.							
In addition to the UWNQC transfer forms and the medical records faxed, is there anything else the OOH provider should routinely provide?	NO	NO	NO	NO	NO	NO	NO	NO
To which department should the patient go?	As instructed by MFM physician.	As instructed by MFM physician.	As instructed by MFM physician.	As instructed by MFM physician.	As instructed by MFM physician.	As instructed by MFM physician.	University of Utah Hospital Clinic-5 Pediatrics	EMS will determine.
In addition to the OOH provider, how many people may accompany the patient?	Labor and Delivery and Postpartum Units allow 5 visitors, not including the midwife or doula. University of Utah considers the transferring midwife to be an important part of the woman's support team.						N/A	2
Anything else?	University of Utah is developing a specific policy regarding well newborns that accompany admitted mothers. Please refer to this policy for details, when available.							
Post-Transfer Communication								
How will the hospital provider report back to the OOH provider on the patient's hospital course?	We will use the **UWNQC Maternal Transfer Form** to find up-to-date and accurate contact information for the transferring midwife. Updates will be given by phone during the hospital admission. The hospital provider will coordinate follow-up care prior to discharge. For all maternal admissions, relevant medical records including admission history and physical, delivery note (if appropriate), and discharge summary will be sent to the referring midwife in a timely fashion.						Follow-up care will be coordinated prior to discharge. For all admitted infants, a discharge summary will be sent to the midwife identified on the **UWNQC Neonatal Transfer Form.**	

*Non-urgent is defined as a condition where the patient needs medical attention, but the situation is not life-threatening, and a delay of up to hours is not likely to significantly affect the outcome.

**Urgent is defined as a condition where the patient needs immediate medical attention to prevent serious injury or death.

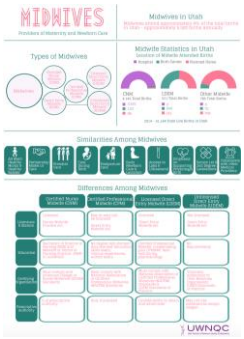
Feedback: Transfer Process & Forms

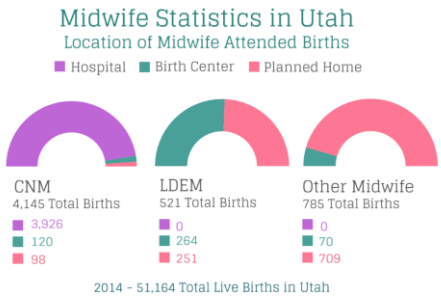
- We need a forum to collect feedback on:
  - -What is working
  - -What isn't working
  - -General concerns and observations
  - -Use of the transfer forms and other tools
- Need to collect de-identified information
- Goal of identifying key themes



Midwife Infographic

- Educational reference regarding midwifes in Utah
  - Types
  - Statistics
  - Similarities & differences





Future Directions

- New Out-of-Hospital Birth Report to be published 2017
  - Eye toward future publication opportunities
- Transfer algorithms for all facilities
- Internal Quality Measures
  - E.g., Can we accurately identify intended OOH Birth Transfers?

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Julia Johnson, MPH
Laurie Baksh, MPH

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Prevention of Preterm Birth: The Role of Highly Effective Reversible Contraception

David Turok, MD, MPH
October 24, 2016

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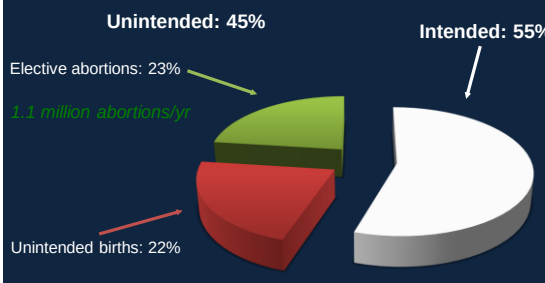
Contraception is currently too hard
&
It's too important for us to not do a better job

- **The Big Goal** → Decrease PTB
- **The Goal** → Meeting contraceptive needs
- **The Path** → Improving access to all contraceptive methods, especially HERC

Unintended Pregnancy in the U.S.



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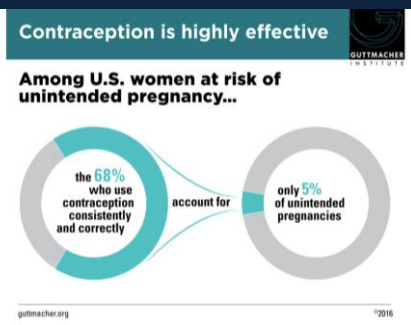
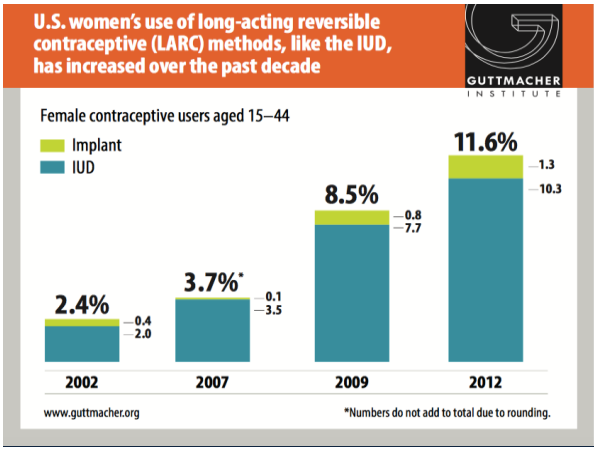
Finer and Zolna. NEJM 2016;374:843-52.





Highly Effective Contraception Can Play an Important Role in Reducing PTB

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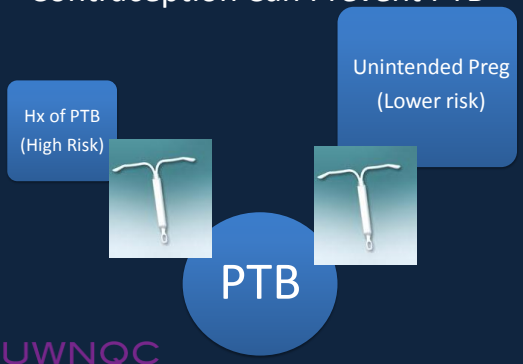
Contraception Can Prevent PTB



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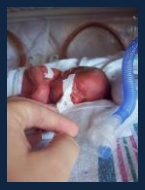
Unintended Pregnancy Challenges Children



- Increased rates of preterm birth
- More NICU stays
- More likely to die in the first year of life
- Less likely to graduate high school

Brown & Eisenberg
The Best Intentions: Unintended Pregnancy and the Well-Being of Children and Families. Institute of Medicine, 1995

Family Planning = Big Time Cost Savings

$7.09

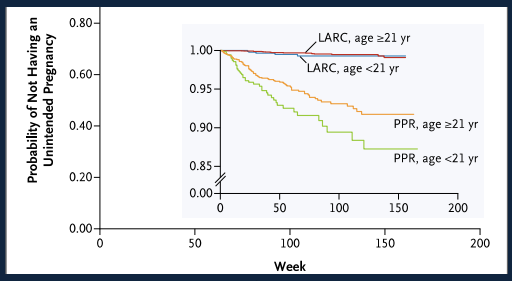
BIGGER FOR HIGH RISK WOMEN

Societal cost of prematurity = $26.2 Billion

Frost JJ et al. The Milbank Quarterly, 2014.
Preterm Birth: Causes, Consequences, and Prevention. Nationalacademies.org

An Experiment in St. Louis

CHOICE: Probability of UIP



Winner et al. NEJM 2012:366:1998-2007.

Set It and Forget It

Highly Effective Reversible Contraception

Copper T380A

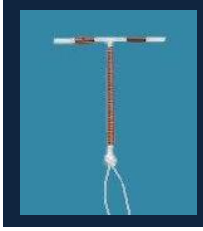
- Hormone Free
- 12 yrs use

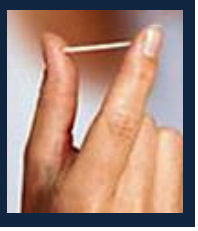
Mirena or Liletta IUD

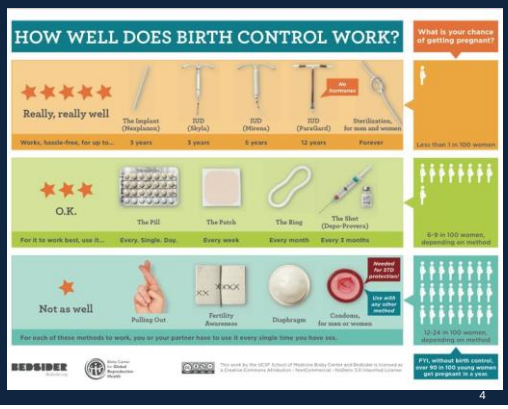
- levonorgestrel released daily
- 5 years use

Implanon

- Etonorgestrel
- 3 years use







Two Utah Examples of Increasing HERC Access

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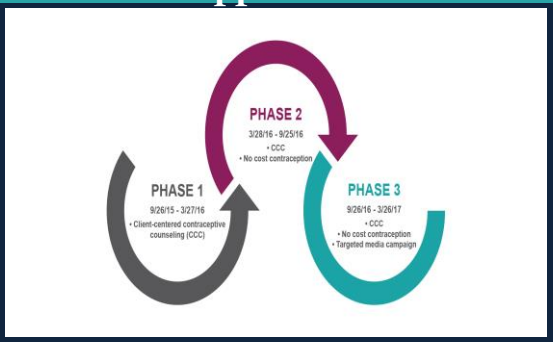
#1) Increasing Overall Contraceptive Access in SLC

The HER Salt Lake Contraceptive Initiative

Study Approach

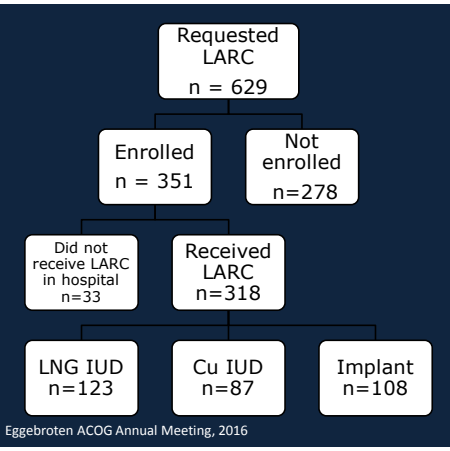


Sponsors and Collaborators

An Anonymous Foundation

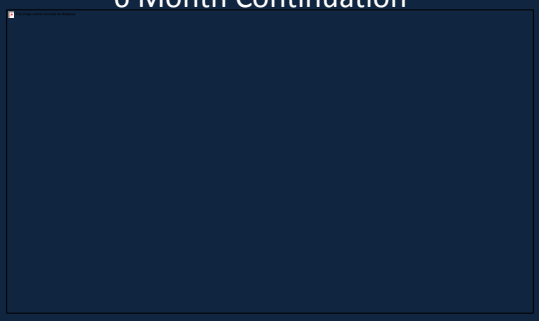
Community Stakeholders

#2) Increasing Postpartum HERC Access in SLC



Eggebroten ACOG Annual Meeting, 2016

In-hospital Postpartum IUD & Implants 6 Month Continuation



Eggebroten ACOG Annual Meeting, 2016

Already Saving Utah Money

- LARC Program & other research projects
- 5,000 IUDs and Implanon devices have been inserted
- 1210 unintended pregnancies prevented
- Saved the state $15.4 million in Medicaid expenditures

Liletta™ (levonorgestrel-releasing intrauterine system) 52 mg

US Medical Eligibility Criteria
(US-MEC) for contraceptive use

- CDC coordinated, evidence based contraceptive
  - Characteristics
    - Age
    - Parity
    - Postpartum
  - Diseases
    - Diabetes
    - Migraines

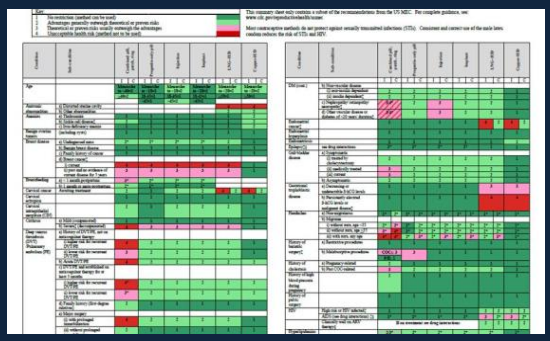
US MEC Categories

Category 1
Use!

Category 2
Consider & Use!

Category 3
Consider & maybe Don't use!

Category 4
Don't use



Download the chart or get the app!

CDC MEC for the Postpartum Period

Condition	Sub-Condition	CHC	POP	Injection	Implant	LNG-IUD	Cu-IUD
Postpartum (*see also Breastfeeding*)	a) <21 days	4	1	1	1		
	b) 21 days to 42 days						
	i) with other risk factors for venous thromboembolism (VTE)	3*	1	1	1		
	ii) without other risk factors for VTE	2	1	1	1		
	c) >42 days	1	1	1	1		
Postpartum (*in breastfeeding or non-breastfeeding women, including post-cesarean section*)	a) <10 minutes after delivery of the placenta					2	1
	b) 10 minutes after delivery of the placenta to <4 weeks					2	2
	c) ≥4 weeks					1	1
	d) Puerperal sepsis					4	4
Pregnancy		NA*	NA*	NA*	NA*	4*	4*

CDC MEC for Breastfeeding

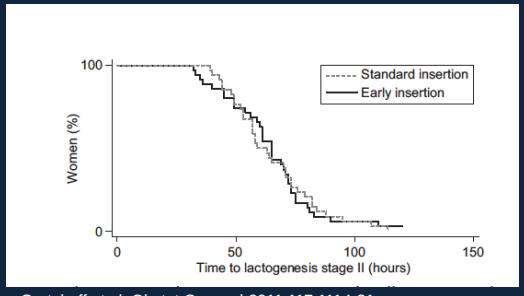
Condition	Sub-Condition	CHC	POP	Injection	Implant	LNG-IUD	Cu-IUD
Breastfeeding (*see also Postpartum*)	a) <1 month postpartum	3*	2*	2*	2*		
	b) 1 month or more postpartum	2*	1*	1*	1*		

Let's slay the 6 week postpartum visit myth forever

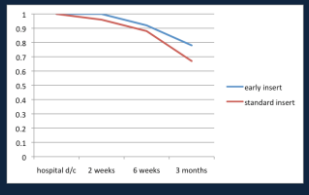
Have a plan in place before birth and execute it within 4 weeks

*43% of women resume sex before 6 weeks

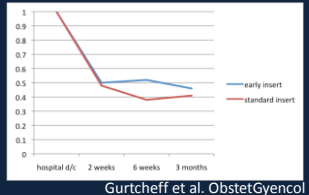
RCT of PP Implant In-Hospital vs. Delayed



Gurtcheff et al. Obstet Gyencol 2011;117:1114-21.



Proportion of participants with **any** breastfeeding at each follow-up time period (p=NS)



Proportion of participants **fully** breastfeeding at each follow-up time period (p=NS)

Gurtcheff et al. ObstetGyencol 2011;117:1114-21

Conclusion

- **<u>In order to</u>** → Decrease PTB
- **<u>We need to</u>** → Meet contraceptive needs
- **<u>Via</u>** → Improving access to all contraceptive methods, especially IUDs and implants

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Questions?

Thank You

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